K120330

APR - 2 2012

1 510(k) Summary of Safety & Effectiveness

(as required by 21 CFR 807.92)

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Penumbra Inc. is providing the summary of Substantial Equivalence for the Penumbra Coil System/Penumbra Coil 400™.

1.1 Sponsor/Applicant Name and Address

Penumbra, Inc.
1351 Harbor Bay Parkway
Alameda, CA 94502

1.2 Sponsor Contact Information

Emilly Tojima Nurthen
Penumbra, Inc.
Regulatory Affairs Program Manager
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E-MAIL: emilly.nurthen@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

March 20, 2012

1.4 Device Trade or Proprietary Name

Penumbra Coil System/Penumbra Coil 400™

1.5 Device Classification

Device, Vascular and Neurovascular Embolization (Product Code: HCG& KRD)

1.6 Predicate Devices

Name of Predicate Device	510(k) Number
Penumbra Coil System/Penumbra Coil 400	K103305

1.7 Predicate Device Comparison

The Penumbra Coil System/Penumbra Coil 400, subject of this 510(k), has the same technological characteristics as the predicate device, and the change is limited to revised product labeling.

1.8 Device Description

The Penumbra Coil System consists of the following components, which are sold separately:

- Standard Complex Coils attached to detachment pusher
- Soft Complex Coils attached to detachment pusher
- J Soft Coils attached to detachment pusher
- Curve Extra Soft Coils attached to detachment pusher
- Curve Complex Extra Soft Coils attached to detachment pusher
- Detachment Handle

The coils are primarily manufactured from platinum wire and Nitinol wire. The coils are attached to a stainless steel / polymer detachment pusher. The coils are available in varying secondary diameters and shapes based on coil type.

The Penumbra Coils are sterile, non-pyrogenic and intended for single use only. The Penumbra Detachment Handle is sterile, non-pyrogenic and may be used to detach multiple coils within a single patient procedure.

1.9 Intended Use

The Penumbra Coil System is intended for the embolization of:

- Intracranial aneurysms
- Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae
- Arterial and venous embolizations in the peripheral vasculature

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1.10 Comparison to predicate Device

	Penumbra Embolization Coil	Penumbra Embolization Coil
510(k) No.	K103305	To be K120330
Classification	Class II, HCG, KRD	Class II, HCG, KRD
Indication	Intended for the embolization of: • Intracranial aneurysms • Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae • Arterial and venous embolizations in the peripheral vasculature	Same
Materials	Coil: Platinum/tungsten, Nitinol Pusher: stainless steel, polymer	Same
Sterilization	EtO	Same
Shelf-Life	36-Months	Same

1.11 Summary of Non-clinical Data:

1.11.1 Biocompatibility

Biocompatibility tests conducted with Penumbra Coil System were selected in accordance with ISO-10993 -1 guidelines (Biological Evaluation of Medical Devices) for a blood contacting permanent implant device. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices.

ISO-10993 GLP Testing Summary for the Penumbra Coil System

Test	Method	Result
Cytotoxicity	L929 MEM Elution Test	Non-Toxic
Sensitization	Kligman Maximization	Non-Sensitizing
Intracutaneous Reactivity (Irritation)	Intracutaneous Injection Test	Non-Irritant
Systemic Toxicity* (Acute)	ISO Acute Systemic Injection Test	Non-Toxic
Subacute / Subchronic Toxicity	*In vivo* Subacute Toxicity	Non-Toxic
Genotoxicity	Ames test	Non-Mutagenic
	Mouse Lymphoma	Non-Mutagenic
Implantation	*In vivo* Implantation	Non-Irritant
Haemocompatibility	Complement Activation	No greater biological response than corresponding control
	Hemolysis	Non-Hemolytic
	In vivo thrombogenicity	Non-Thrombogenic
Pyrogenicity	USP Material Mediated Rabbit Pyrogen Test	Non-Pyrogenic

In summary, non-clinical testing found the Penumbra Coil System to be biocompatible according to the requirements of ISO 10993-1. Additionally, the product was found to be non-pyrogenic.

1.11.2 Design Verification (Bench-Top Testing)

Design Verification testing was conducted to evaluate the physical and mechanical properties of the Penumbra Coil System. All studies were conducted using good scientific practices and statistical sampling methods as required by the Penumbra Design Control procedures. All testing was performed using units which were 2x sterilized and met finished goods release requirements. The tests performed on the Penumbra Coil System included:

- Dimensional / Visual Inspection (all sizes)
- Joint Tensile Strength
- Fatigue
- Friction

- Torsion
- Stiffness
- Corrosion
- Handle Function
- MRI Compatibility
- GLP Simulated Use

All tests performed passed successfully.

The physical, mechanical and performance testing of the subject Penumbra Coil System demonstrate that the product is safe and effective for its labeled indications and is Substantially Equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Penumbra, Inc.
c/o Mr. Seth Schulman
Director, Regulatory Affairs
1351 Harbor Bay Parkway
Alameda, CA 94502

APR - 2 2012

Re: K120330
Trade/Device Name: Penumbra Coil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: February 1, 2012
Received: February 2, 2012

Dear Mr. Schulman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120330

Device Name: Penumbra Coil System

Indications For Use:

The Penumbra Coil System is indicated for the embolization of:

- Intracranial aneurysms
- Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae
- Arterial and venous embolizations in the peripheral vasculature

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JOE HUTTER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K120330